

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS

1-16. (canceled)

17. (currently amended) An injectable or implantable formulation comprising:

at least one beneficial agent selected from the group consisting of a peptide, a protein, a nucleotide, a hormone, a virus, an antibody, and pharmaceutically acceptable salts thereof; and

a sterile, non-aqueous, single-phase biocompatible vehicle comprising a solvent, a surfactant, and a polymer, wherein the solvent, the surfactant, and the polymer are not the same, wherein the solvent is lauryl lactate or lauryl alcohol, the surfactant is selected from the group consisting of esters of polyhydric alcohols, ethoxylated castor oil, polysorbates, esters or ethers of saturated alcohols, and polyoxyethylenepolyoxypropylene block copolymers, and the polymer is selected from the group consisting of polyesters, pyrrolidones, esters or ethers of unsaturated alcohols, and polyoxyethylenepolyoxypropylene block copolymers, and wherein the solvent, the surfactant, and the polymer are selected and formulated such that the non-aqueous, single-phase biocompatible vehicle exhibits a viscosity capable of suspending the at least one beneficial agent, and wherein the formulation is physically stable at body temperature for at least one month.

18. (currently amended) A non-aqueous formulation comprising at least one sterile beneficial agent uniformly suspended in a vehicle comprising a solvent, a surfactant, and a polymer, wherein said at least one beneficial agent is selected from the group consisting of a peptide, a protein, a nucleotide, a hormone, a virus, an antibody, and pharmaceutically acceptable salts thereof, wherein the solvent is lauryl lactate or lauryl alcohol, the surfactant is selected from the group consisting of esters of polyhydric alcohols, ethoxylated castor oil, polysorbates, esters or ethers of saturated alcohols, and polyoxyethylenepolyoxypropylene block copolymers, and the polymer is selected from the group consisting of polyesters, pyrrolidones, esters or ethers of unsaturated alcohols, and polyoxyethylenepolyoxypropylene block copolymers, and wherein the solvent, the surfactant, and the polymer are selected and formulated such that the vehicle is a

sterile, non-aqueous, single-phase biocompatible vehicle that exhibits a viscosity capable of suspending the at least one beneficial agent, and wherein the formulation is physically stable at body temperature for at least one month.

19. (canceled)

20. (previously presented) The formulation of claim 17, wherein the at least one beneficial agent comprises at least about 0.1% (w/w) of the formulation.

21. (previously presented) The formulation of claim 17, wherein the at least one beneficial agent comprises at least about 10% (w/w) of the formulation.

22. (canceled)

23. (previously presented) The formulation of claim 17, wherein the at least one beneficial agent is a protein.

24. (previously presented) The formulation of claim 17, wherein the at least one beneficial agent and the non-aqueous, single-phase biocompatible vehicle are selected and formulated such that the formulation is stable at 65°C for at least about two months.

25. (previously presented) The formulation of claim 17, wherein the at least one beneficial agent and the non-aqueous, single-phase biocompatible vehicle are selected and formulated such that the formulation is stable at 37°C for at least about three months.

26. (previously presented) The formulation of claim 17, wherein the at least one beneficial agent and the non-aqueous, single-phase biocompatible vehicle are selected and formulated such that the formulation is stable at 37°C for at least about one year.

27. (previously presented) The formulation of claim 17, wherein the at least one beneficial agent and the non-aqueous, single-phase biocompatible vehicle are selected and formulated such that the formulation is adapted for use in an implantable drug delivery device.

28. (canceled)

29. (previously presented) The formulation of claim 17, wherein the non-aqueous, single-phase biocompatible vehicle further comprises an antioxidant.

30. (previously presented) The formulation of claim 17, wherein the at least one beneficial agent comprises a beneficial agent which has been dried to a low moisture content prior to incorporation in the formulation.

31. (previously presented) The formulation of claim 17, wherein the at least one beneficial agent and the non-aqueous, single-phase biocompatible vehicle are selected and formulated such that the formulation is stable after sterilization.

32. (canceled)

33. (currently amended) A method for preparing an injectable or implantable formulation comprising at least one beneficial agent and a non-aqueous, single-phase biocompatible vehicle comprising a solvent, a surfactant, and a polymer, wherein the solvent, the surfactant, and the polymer are not the same, wherein the solvent is lauryl lactate or lauryl alcohol, the surfactant is selected from the group consisting of esters of polyhydric alcohols, ethoxylated castor oil, polysorbates, esters or ethers of saturated alcohols, and polyoxyethylenepolyoxypropylene block copolymers, and the polymer is selected from the group consisting of polyesters, pyrrolidones, esters or ethers of unsaturated alcohols, and polyoxyethylenepolyoxypropylene block copolymers, ~~and~~ wherein the solvent, the surfactant, and the polymer are selected and formulated such that the non-aqueous, single-phase biocompatible vehicle exhibits a viscosity capable of suspending the at least one beneficial agent, the method comprising:

preparing a sterile, substantially uniform injectable or implantable suspension of the at least one beneficial agent by combining the non-aqueous, single-phase biocompatible vehicle and the at least one beneficial agent under dry conditions, under vacuum and at elevated temperature, wherein the at least one beneficial agent is selected from the group consisting of a peptide, a protein, a nucleotide, a hormone, a virus, an antibody, and pharmaceutically acceptable salts thereof; and

allowing the sterile, substantially uniform suspension to cool to room temperature.

34. (previously presented) The method of claim 33, wherein preparing a substantially uniform suspension of the at least one beneficial agent comprises preparing a substantially uniform suspension having at least about 0.1% (w/w) of the at least one beneficial agent.

35. (previously presented) The method of claim 33, wherein preparing a substantially uniform suspension of the at least one beneficial agent comprises preparing a substantially uniform suspension having at least about 10% (w/w) of the at least one beneficial agent.

36. (currently amended) A method for treating a subject suffering from a condition which may be alleviated by administration of a beneficial agent comprising administering to the subject a therapeutically effective amount of a sterile, injectable or implantable formulation comprising:

at least one beneficial agent selected from the group consisting of a peptide, a protein, a nucleotide, a hormone, a virus, an antibody, and pharmaceutically acceptable salts thereof; and

a non-aqueous, single-phase biocompatible vehicle comprising a solvent, a surfactant, and a polymer, wherein the solvent, the surfactant, and the polymer are not the same,

wherein the solvent is lauryl lactate or lauryl alcohol, the surfactant is selected from the group consisting of esters of polyhydric alcohols, ethoxylated castor oil, polysorbates, esters or ethers of saturated alcohols, and polyoxyethylenepolyoxypropylene block copolymers, and the polymer is selected from the group consisting of polyesters, pyrrolidones, esters or ethers of unsaturated alcohols, and polyoxyethylenepolyoxypropylene block copolymers, and wherein the solvent, the surfactant, and the polymer are selected and formulated such that the non-aqueous, single-phase biocompatible vehicle exhibits a viscosity capable of suspending the at least one beneficial agent.

37. (previously presented) The method of claim 36, wherein administering to the subject a therapeutically effective amount of the formulation comprises parenterally administering to the subject a therapeutically effective amount of the formulation.

38. (previously presented) The method of claim 36, wherein administering to the subject a therapeutically effective amount of the formulation comprises administering the formulation to the subject continuously over a long term.

39. (previously presented) The method of claim 36, wherein administering to the subject a therapeutically effective amount of the formulation comprises administering the formulation to the subject from an implantable drug delivery system.

40. (previously presented) The method of claim 36, wherein administering to the subject a therapeutically effective amount of the formulation comprises administering the formulation to the subject daily for a period of time selected from the group consisting of about three months, about six months, and about twelve months.

41. (previously presented) The method of claim 40, wherein administering to the subject a therapeutically effective amount of the formulation comprises administering the formulation to the subject from an implantable drug delivery system.

42-48. (canceled)

49. (previously presented) The formulation of claim 17, wherein the non-aqueous, single-phase biocompatible vehicle comprises from about 30% to about 50% of the solvent, from about 5% to about 20% of the surfactant, and from about 5% to about 60% of the polymer.

50. (previously presented) The formulation of claim 17, wherein the polymer is polyvinylpyrrolidone and the surfactant is polysorbate.

51. (previously presented) The formulation of claim 17, wherein the polymer is polyvinylpyrrolidone and the surfactant is glycerol monolaurate.

52-53. (canceled)